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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,963	12/03/2003	David Ernest Hartley	PA-5351-RFB	4386

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COOK GROUP PATENT OFFICE
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EXAMINER

KOTINI, PAVITRA

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,963

Applicant(s)

HARTLEY ET AL.

Examiner

Pavitra Kotini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "trigger mechanism", "means at the distal end to release of the elongate catheter to release the trigger wire arrangement", and "item 35" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmaz et al.

Regarding **claim 1**, Palmaz discloses a plurality of self expanding stents (fig. 9, 21) together defining an elongate substantially cylindrical lumen wall engaging surface (fig. 9) and at least one of the stents having a biocompatible graft material (col.9, line 66 – col.10, line 5) cover defining a covered portion (fig. 10A, 202).

Regarding **claim 2**, Palmaz discloses the cover encompasses at least two of the plurality of stents (fig. 10A) and the cover is stitched or otherwise fastened to the stents in the covered portion (col.10, lines 10-18, lines 23-27).

Regarding **claim 3**, Palmaz discloses the covered portion of the prosthesis is at the proximal end of the plurality of stents (fig. 1).

Regarding **claim 4**, Palmaz discloses uncovered stents extend away from the covered portion and are linked by flexible links (fig. 1 & fig. 9, 205).

Regarding **claim 5**, Palmaz discloses uncovered stents extend away from the covered portion and are linked by a thread or fibre (col.9, lines 20-24).

Regarding **claim 9**, Palmaz discloses the uncovered portion is in the form of a self expanding spiral stent of zig-zag configuration (fig. 10B, 167).

Regarding **claim 10**, Palmaz discloses the cylindrical body in an expanded state having at least one self expanding stent covered by a bio-compatible graft material (col.9, line 66 – col.10, line 5) and a self expanding stent assembly extending from a distal end thereof (fig. 10A & 10B).

Regarding **claim 12**, Palmaz discloses the self-expanding stent assembly extending from a distal end of the biocompatible graft material is formed from a biocompatible and biodegradable mesh material (col.9, lines 5-10).

Regarding **claim 13**, Palmaz discloses the cylindrical body in an expanded state having at least one self expanding stent (fig. 10A) covered by a bio-compatible graft material (col.9, line 66 – col.10, line 5) and a self expanding stent assembly extending from a distal end thereof (fig. 10B), and an elongate catheter (fig. 3, lines 181) adapted to be deployed over a guide wire (fig.2, 200), a nose cone (fig.4 184) at the proximal end of the elongate catheter, a trigger wire arrangement (fig.5, 182; col.11, lines 41-47), a sheath arrangement (fig.3, 186) over the elongate catheter, means at the distal end of the elongate catheter to release the trigger wire arrangement (col.12, lines 25-28), and means to withdraw the sheath arrangement (col.12, lines 4-5, lines 44-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (US-5571170) in view of Nobles et al. (US-20020049453). Palmaz discloses the invention substantially as claimed above.

Palmaz does not disclose suture knot to be at least one of a half hitch, a thumb knot, two half hitches or a clove hitch. However, Nobles et al teaches suturing using a half hitch knot. This type of knot would have the apparent advantage of assisting in linking two elements together or for placing one knot on top of another. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the suture of stents together as disclosed by Palmz by using a half hitch knot as taught by Nobles.

Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (US-5571170) in view of Lazarus (5662700). Palmaz discloses the invention substantially as claimed above.

Palmaz does not disclose barbs at the proximal end of a stent nor graft. However, Lazarus teaches barbs (fig. 4, 72) at the end of a stent to facilitate attachment of the stent to the wall. These wall-engaging members would have the apparent advantage of retaining the stent in place. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the stent or graft as disclosed by Palmaz to include barbs at the proximal end as taught by Lazarus.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (US-5571170) in view of Lau et al (US-6309412). Palmaz discloses at least three

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covered stents of the plurality each of the zig-zag type and up to eight or ten uncovered stents of the plurality.

Palmaz does not disclose the stents constructed from stainless steel or Nitinol. However, Lau et al teaches stent formed from a tubing of stainless steel or Nitinol (col.6, lines 64-66). This material would provide the apparent advantage of making the stent biocompatible. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the stent disclosed by Palmaz to be made of the material taught by Lau.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (US-5571170) in view of Evans et al (US-6508782). Palmaz discloses an elongate catheter and a nose cone.

Palmaz does not disclose a means for supplying an angiographic contrast medium through the catheter and ports on the nose cone. However, Evans teaches a catheter with a bulbous tip and ports that can discharge angiographic dye. This arrangement would have the apparent advantage of enabling visualization of the vasculature. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the nose cone of the catheter as disclosed by Palmaz to include ports as taught by Evans to gain the advantage stated above.

Allowable Subject Matter

Claims 15 and 16 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pavitra Kotini
AU 3731


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
